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UNITED STATES DISTRICT COURT
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                 EASTERN DISTRICT OF VIRGINIA
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                      ALEXANDRIA DIVISION
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   UNITED STATES OF AMERICA,
                                  Case 1:14-cr-00397
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                Plaintiff,
5
                                   Alexandria, Virginia
          v.
                                   September 17, 2015
  DAVID E. BURKE,
                                   9:04 a.m.
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7
                Defendant.
                                  Pages 1 - 37
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                   TRANSCRIPT OF SENTENCING
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            BEFORE THE HONORABLE ANTHONY J. TRENGA
11
              UNITED STATES DISTRICT COURT JUDGE
12
  APPEARANCES:
  FOR THE PLAINTIFF:
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24 ∥THE DEFENDANT, DAVID E. BURKE, IN PERSON
25
       COMPUTERIZED TRANSCRIPTION OF STENOGRAPHIC NOTES
     Rhonda F. Montgomery OCR-USDC/EDVA (703) 299-4599
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THE CLERK: Criminal Case 1:14-cr-397, United
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   States of America v. David E. Burke.
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             Will counsel please note their appearances
 4 for the record.
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             MR. DWYER: Good morning, Your Honor. Kellen
  Dwyer for the United States.
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             THE COURT: Good morning.
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             MR. AGNIFILO: Good morning, Your Honor.
  Marc Agnifilo for David Burke with Stuart Sears as
  well.
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             THE COURT: All right. Welcome.
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             We're here for sentencing. Have you provided
13 La copy of the presentence report to Mr. Burke, and have
  you reviewed it with him?
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             MR. AGNIFILO: I have, Your Honor. Thank
16 you.
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             THE COURT: All right. Any objections other
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  than what's in your filings?
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             MR. AGNIFILO: Only in the filings, Judge.
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             THE COURT: All right. Do you want to be
21 heard any further on your objections?
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             MR. AGNIFILO: Yes, briefly. Thank you,
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  Judge.
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             We have two guidelines-based objections, and
25 II suppose they're somewhat related. The heart of the
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lissue, Judge, is that Mr. Burke was -- essentially, he
  was a salesman. That's what he was.
                                         He didn't run
  this company. He didn't truly have any independent
   discretion over how the company ran. He basically had
  to do everything at the behest of the person who was
  the principal of the company, who was his direct boss,
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  this person named Tzvi Lexier. So he really didn't
  have any independent discretion.
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             I know I make these arguments in my papers.
  II don't want to belabor them, but I think it relates
  both to the role in the offense and also to the amount
  of loss that is going to be attributed to Mr. Burke.
             I think at the end of the day, Mr. Burke
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  didn't really have any way of knowing the full amount
  that Tzvi Lexier and the company as a whole was making.
  So just for under principals of relevant conduct,
  that's why I asked, Your Honor, to keep the loss amount
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  at essentially the commissions that Mr. Burke he,
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  himself, made.
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             So the two issues, I suppose, are related.
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  know we go into this at length in our papers. I don't
  need to belabor it at this point.
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             Thank you, Judge.
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                         Counsel, any objections?
             THE COURT:
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             MR. DWYER:
                         No, Your Honor.
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1 If I could be heard in response. 2 THE COURT: All right. 3 MR. DWYER: First, on Mr. Burke's leadership 4 Irole, he was the director of sales and trained and supervised the rest of the sales staff. He also 5 provided detailed instructions to the drop-shippers and 7 coordinated the shipping from overseas to the American drop-shippers and eventually to the clients. gave advice to the overseas shippers about how they could sneak these drugs and devices past U.S. Customs. 11 From the papers, the defense has the idea 12 that because the Lexiers owned the company and 13 Mr. Burke didn't that he can't have a leadership role. That's legally incorrect. You don't have to be an 15 wher of a company. You don't even have to be the highest person in an organization to have a leadership 17 role. That's why the enhancement says that there's a 18 4-point enhancement if you're an organizer and leader, 19 not the organizer or leader. 20 Mr. Burke ran the day-to-day operations. The 21 company was owned by the Lexier family. 22 THE COURT: It wasn't clear to me what that 23 exactly meant in the filings, his involvement in the 2.4 day-to-day operations.

MR. DWYER:

Sure. If I could give you maybe

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a little bit on the structure of the organization.
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             THE COURT:
                         All right.
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             MR. DWYER: Dr. Lexier and his wife, Sophie,
  owned the company but had very little involvement at
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5
  all.
         Their son, Tsvi Lexier, was the CEO and also had
  an equity interest. The very next person below that is
  Mr. Burke. Mr. Lexier was not nearly as hands-on as
  Mr. Burke was.
9
             As I said, Mr. Burke worked out of Toronto,
  supervised the sales staff, the people who would
  actually call and try to get clients. Then when they
12 got an order, Mr. Burke would coordinate with the
13
  overseas shippers who would ship the drugs to the
  drop-shippers in the United States, like David Stein
15
  and Rivka Rabi. These people are getting direct orders
  from Mr. Burke. We included some messages in our
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  papers.
18
             THE COURT: Right.
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             MR. DWYER:
                         There's many, many more where
  Mr. Burke is contacting David Stein every day saying,
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  What about this shipment? Has this gone out?
  gone out? He's contacting Rivka Rabi, who Your Honor
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  has gotten to know a little bit. She was no leader.
  She was taking direct orders from Mr. Burke.
25
             So in terms of kind of who everybody in the
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organization would report up to, it would be Mr. Burke.
  Very few of them had direct contact with Tzvi Lexier.
  The only person who had much contact with Tzvi Lexier
   was Burke. You'll see in a text message just weeks
  before he was arrested, Mr. Burke himself says, I've
  been the most influential part of this company since
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  day one.
             This is reflected in the salary that he made.
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  Mr. Burke actually made more money from the company
  than Tzvi Lexier and almost as much as Tzvi Lexier,
  Reuven Mirlis, and Sophie Lexier put together.
12 Mr. Burke made $1.3 million versus $900,000 that Tzvi
13
  made, $415,000 that Reuven made, and Sophie wasn't paid
  any money. She was just kind of on the board as a
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  figurehead.
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             So, you know, the idea that Mr. Burke was
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  ∥just kind of following orders and didn't have any
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  discretion just doesn't fit the facts.
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             If I can be heard briefly on the loss amount.
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             THE COURT:
                         Yes.
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             MR. DWYER:
                         The company as a whole made over
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  $30 million in proceeds. The government has stated
  \parallelthat the enhancement should be 20 points for a loss
  between 7 and 20 million. There's any number of ways
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  to get to that number, but probably the least
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controversial is that --
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             You know, Mr. Burke admits that he made
  $1.3 million.
                 He admits that that was almost entirely
  from commissions. So even if he were just looking at
  the drugs that he himself sold to make those
  commissions, that's easily over $7 million because the
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  commission, from our understanding, is somewhere
  between 15 and 20 percent of the sales.
9
             If you're making $1.3 million in commission,
  you're selling way over $7 million in drugs, and that's
  not even counting the rest that was foreseeable as
  someone who was overseeing others.
             Finally, if I could just briefly be heard on
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  the comparison to the Gallant sentencing. In the
  papers, Mr. Burke said that he should be compared to
  Mr. Rochelle, who was a salesman at Gallant who was
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  recently sentenced to 12 months. Mr. Rochelle, first
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  of all, had a 5K motion because he was a cooperator.
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  Mr. Rochelle only made $80,000 in commissions versus
   $1.3 million for Mr. Burke.
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             THE COURT: All right. Thank you.
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             Counsel.
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             MR. AGNIFILO: If I could, Your Honor.
                                                     Thank
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  you.
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THE COURT:

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             MR. AGNIFILO: I don't want to put too much
   emphasis on the formal corporate structure because I
  don't know that that's really here nor there.
  he had no role in the formal corporate structure
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  whatsoever. He was just a salesman. To say that he
  was the manager of the sales force, he did have that
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  title, but he had no equity in the business.
  know at the end of the day -- I don't know what the
  Lexiers' personal finances are, but I think as owners
  of the business, there's probably ways of them
  realizing income from the business that they
12
  essentially owned without it being deemed a salary.
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             The point that, I think, is important is that
  he -- at most, Mr. Burke is a mid-level type executive.
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  I mean, there's nothing he can do truly on his own.
  Everything he does is at the whim of Tzvi Lexier, and I
  \parallelthink the e-mail -- rather, the text message that the
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  government refers to is a revealing one. It's David
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  Burke essentially begging Tzvi to view him as valuable,
  and there's two components to it. The government
  focuses on, I guess, the self-aggrandizing component:
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  Look, Tzvi, I've been good for the company. I help
  you. I do a lot of things.
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             But the reading between the lines, I think,
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   is really the heart and soul of that communication
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which is I need you, my boss, to recognize me.
  you, my boss, to recognize me. I mean, there's a clear
  superior/inferior position between those two people,
   which is why he's sending that message basically asking
  Itzvi to recognize him as a valuable member of the
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  company.
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             He was a valuable member of the company
  certainly, but here he is talking to his boss.
  Obviously, he's feeling he's not getting the
  recognition that he deserves, and the point of the fact
   that he's even looking for this recognition is that
12 he's looking for recognition from someone who is
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  clearly a superior. I mean someone who can fire him,
  who can reduce his commissions, who can increase his
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  commissions. I mean, there's really nothing that David
  Burke is doing truly on his own.
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             He was an active salesman. I mean, the one
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  thing, I think, that we probably agree with the
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  government on is he was the most prolific, the most
  active, the most successful salesman in the company.
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  think we agree on that, and I think that's common
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  ground.
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             In terms of the overall decision-making for
  the company, direction of the company, I mean, at one
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  point -- I know I reference it in my papers a few times
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because I think it's a significant point -- Tzvi Lexier seems to start another business in Montreal other than the business he has in Toronto, and he has three known principals -- I don't identify them in the public filing -- meet with David Burke basically so Burke could tell them, This is how you sell product.

Now, on the one hand, you could say, Oh, David Burke is playing some supervisory type role, but lit really isn't because he has nothing to do with the Montreal business. That's all the Lexier family. The 11 Lexier family decided, as a matter of overall corporate 12 governance, to start another business in Montreal that has nothing to do with Burke. So it's just one of the ways of highlighting the discrepancy in the different roles.

I think what's also significant, Judge, is David Burke -- and I know that the rough equivalent of David Burke in the Gallant Pharma case got an actual 5K. We, quite frankly, tried get a 5K, and it didn't work out. I think the reason it didn't work out is litself somewhat significant. The first thing that David Burke did when he was arrested is he spoke with \parallel the agents. He was on the plane to Florida to see his father. He gets arrested. He speaks with the agents. He speaks with the agents, I think, at fair length and

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gives them a lot of details. The initial word from the government was that this was valuable information and we're going to pursue it.

The problem is that Mr. Burke was arrested in Florida. He was in Florida for a number of days. Just the way the Bureau of Prisons gets folks around the country, he was in Florida. Then he was in Oklahoma City. Then he was in Atlanta. We just couldn't quite get it all set up -- and it's difficult to do when a prisoner is in transit -- to have another interview. By the time he got to Virginia -- and I don't say this through faulting the government in the least. I think the government had him in and listened to him. But by the time he got to Virginia, the government didn't need him. I think others had stepped up, others who were lower in the food chain than Mr. Burke, and the government made a decision that the government often does, that we're going to use these folks and we're not going to use this guy. That's basically what happened.

Nonetheless, we brought Mr. Burke in to the government. We were there for many, many hours, and I think he provided important information. I don't know because the government does their things. And I don't always know what the government does, and it's not my business. But I know that he provided important

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information, I think, that went to the companies. the end of the day, the companies pleaded guilty, and others pled guilty in this case.

I'm not saying that it's because of Mr. Burke, but I know that Mr. Burke -- because I sat in the meeting -- gave a tremendous amount of ||information that, I think, was critical as part of the government's case against the company. Not that the government maybe didn't have similar information in texts or from other folks, but I think Mr. Burke is uniquely positioned to give information against Tzvi 12 Lexier and the Lexier family. And he did. information that the government has.

It's my belief at this point that Mr. Lexier was arrested in Canada and is awaiting extradition to the United States. I think that will certainly round out the case.

I think the all-important question, the question that I've asked myself, and the question I've tried to prepare for Your Honor -- because I think Your Honor would certainly want to know the answer -- is at some point, obviously, Mr. Burke knew this was an ||illegal business. Maybe in the beginning he didn't quite know. Maybe it wasn't clear. Maybe he had sort of drank the proverbial Kool-Aid in the beginning, but

at some point, he knew. He knew flat out, and everybody knew flat out. I don't know what the position of the other defendants are on the case, but at some point, everybody in this business knew it was flat-out illegal. He did too, and he stayed.

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The question, when I'm asking Your Honor for a lenient sentence, is how do I fill that void. do I say to Your Honor in light of that to convince the Court to give him a lenient sentence? I think a lot of things go into this.

I think the first thing is there was a 12 measure of self-esteem he got from this job. really, the first thing he ever did well in his life. He is someone who struggled in school. He had learning differences. I don't mention that just for the merciful aspect of someone with learning differences, but I think it plays a role in the decisions that he made. He had a hard time in school. His parents had to hire a lawyer for him to even stay in school.

Then he goes, and he works for the Lexiers. He's a salesman, and in the beginning, he thinks it's legitimate. Then he thinks, well, maybe it's not fully legitimate, but it seems like maybe it's a gray area. II think that's a term that I've heard a lot in this: It's a gray area.

After the Gallant Pharma case, no one can really think this is a gray area anymore. Everyone can only really see this case for what it was, which is at this point it's illegal. Whether there's a way of doing this legally or not, I don't know. But here it wasn't being done legally. It was being done through different manners of deception. He knew that, and he didn't leave.

The two primary reasons he didn't leave:
One, he was making money for the first time in his
life, and his family needed the money. His wife needed
the money. He needed the money. He was having
expensive fertility treatments. He started at this job
when he was living in his father's basement. This job
not only gave him the money but I guess, in a sense,
almost made him a man. He could take care of his
family. He could move him and his wife out of the
basement. They could get an apartment on their own,
and he could pay for these fertility treatments, which
they're still trying to work through.

Then there's just the money. Your Honor sees people every day who did bad things for money, and this is not different in that regard. But I do think that there are these other aspects to it that are mitigating in nature.

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honest person.

He's been only remorseful since the very second he was arrested. He put his money where his mouth was in that regard and spoke to the government. I mean, I know that some of the other defendants in this case -- and I know the government's position is that they weren't as culpable as Mr. Burke. weren't as immediately remorseful either. I mean, some -- one defendant I'm thinking of in particular pled quilty a week before trial. That's his right, and that happens from time to time. We didn't have that here. He showed remorse. 12 He showed meaningful remorse by speaking to the government off the bat. He told the government flat out: I want to cooperate if you'll have me. It turns out the government doesn't need him or hasn't needed him so far. Then he pled guilty, really, at the earliest opportunity. Your Honor let him out of jail a Ifew months ago. Remember, we had a bail hearing here. He's tried to understand why he did what he did. He's been seeing a therapist. The therapist's letters are in with the letters I gave to Your Honor. He's volunteered at a religious charity. He's tried to

come to terms with this. This is an odd thing for me

to say I suppose, but he's really a fundamentally

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I think in his mind -- and I don't know what
   the medical science turns out to be -- no one was
  getting hurt. Now, I know there's issues with the
  Botox and the cold Botox and the not cold Botox.
  think in his mind for a long time, this was basically
  beating -- the pharmaceutical companies had jacked up
  prices, and this was a way of just getting the same
  products less expensively.
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             Now, obviously, the Achilles' heel for us in
  that argument could be viewed as the Botox issue, but I
   don't think at the end of the day it is because there
  really was a belief in the company that the Botox, even
   if distributed in an uncool state, the worst that would
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  happen is that the Botox wouldn't work.
             THE COURT: Well, there were other cold chain
  products in addition to Botox.
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             MR. AGNIFILO: Yes, that's right, Judge.
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  II think the belief was that it would affect the
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  efficacy of the product, that it wouldn't hurt people.
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  II think that's key to his personal ethics. I think he
  does have a system of personal ethics. I've gotten to
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  know him pretty well over the last several months, and
  I think he would not do anything to hurt people.
  That's not who he is. That's just not who he is.
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             He was in this gray area, and he was in this
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gray area heavy. He continued to do this even after the Gallant Pharma prosecution when he knew that it was no longer a gray area, but so did all the defendants, Judge. All of the defendants in this, I mean, Your Honor has looked at them and their individual characteristics.

I think the similarities between Mr. Burke and, say, David Stein, the similarities outweigh the differences. There's no -- Mr. Burke made more money. That's the first thing that leaps out as a difference, and that's because he was a salesman. He was on commission, and he made money from the commission. He sold a lot of product. But at the end of the day, David Stein -- I think it was \$13 million of product went through David Stein's basement, and David Stein was changing labels. David Stein knew everything about the illegality of the business that Mr. Burke knew.

So I don't know that -- there's admittedly a difference in degree, which is why when I thought what a credible sentence would be for me to ask Your Honor for, I came up with 18 months. I don't think it would be a credible sentence for me to ask for the same sentence as David Stein. I don't think you would view that as a credible argument. So I tried to find a way of showing that, yes, we are worse, and we admit it.

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So we're not asking for an 8-month sentence. We're asking for an 18-month sentence.

Here's why I think, one man thinks that's a reasonable sentence. Your Honor is the only one who will impose sentence, and then that will be the sentence.

I think what the government has done in this case is actually critically important. I think that the government has a mission in this case, and I think \parallel it's actually a good mission. I think the mission that they have in this case is to show the world that this 12 has to stop: You can't do this anymore. Everyone should be on notice after the Gallant case, after this case that this isn't a gray area and this isn't some kind of licensing issue. This is a crime. We have the FDA for a reason. We have the safeguards we have in this country for a reason. I think the government has done a very important job at getting that message out, and the message is out.

I think an 18-month sentence for a salesman, even a lucrative salesman, is a very significant sentence. It's a very significant sentence, I think, as a matter of general deterrence. I think it sends the message out. I think it shows in combination with the forfeiture order that we're signing, in combination with the fines to the corporation, I think, and with the fact that -- and I salute the government for arresting Tzvi Lexier and eventually going to bring him to justice probably right in this courtroom. think the deterrent impact of this sentence is an important goal of sentencing, and I think it's met by an 18-month sentence, which is a significant sentence generally.

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In terms of a sentence for one man and his family, it's a very significant sentence. I mean, he's Itrying to start his life. His wife is here toward the 12 end over there. They're a young couple. They've struggled. They want to have a family. They've tried to have a family. They've engaged in fertility Itreatments to the cost of tens of thousands of dollars to try to do that.

We all know David Burke is going to go to **∥**jail at the end of today, but I think what seems fair and right in a larger sense is that he do his jail term and he come out not too much of an older man so that he and his wife can get on with their lives and get on with their family. He has a lovely family. They have been supportive throughout. His parents, his brothers, 24 sisters, everyone has been supportive throughout. Many of the letters are to Your Honor.

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I just think that an 18-month sentence is a
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  sentence that is -- shows specific and general
  deterrence. It shows respect for the law. I think it
   shows all the things we needed to show under 3553(a).
  It's certainly a serious sentence for Mr. Burke.
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   think it's a sentence that's consistent, in my personal
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  opinion, with the other sentences both in this case and
  the Gallant case. I think a sentence in excess of
  that, I think, would be more heavily weighed against
  Mr. Burke. I think this sentence is in keeping with
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   the way that these cases have been sentenced. I think
  it sends the message that the government deserves sent
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  and the government wants sent.
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             So that's all I have, Judge.
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             THE COURT: All right. Counsel, I don't know
  if you had completed what you wanted to say.
                                                 Is there
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  anything else?
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             MR. DWYER: No, nothing further, Your Honor.
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             THE COURT: All right. Mr. Burke, you have
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   the opportunity to address the Court before it imposes
  sentence. Would you like to say anything, sir?
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             THE DEFENDANT: Yes, Your Honor.
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             I just wanted to apologize to my family, my
  friends, the Court for the embarrassment I've caused,
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  for the crime that I actively participated in, and just
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an overall apology. Over the last nine months, I have
  had plenty of time to review this in my head and go
  over and over. There's really no excuse for what I
   did. Once again, I apologize.
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             THE COURT: Why don't you have a seat.
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             This matter is before the Court for
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  sentencing in the case of United States v. David Eli
  Burke with respect to his conviction on five counts,
  lincluding conspiracy, in violation of Title 18, United
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  States Code, Section 371, a Class D felony, punishable
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  \parallelup to 5 years, a $250,000 fine, a $100 special
  assessment, and 3 years of supervised release;
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  smuggling goods into the United States, in violation of
  Title 18, United States Code, Section 545, a Class C
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  felony, punishable by a term of up to 20 years, a
  $250,000 fine, a $100 special assessment, and 3 years
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  of supervised release; introducing misbranded drugs and
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  devices in interstate commerce, in violation of
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  Title 21, United States Code, Sections 331(a) and
   332(a)(2), a Class E felony, punishable up to 3 years
  in prison, a $10,000 fine, 1 year of supervised
  release; a conviction for unlicensed wholesale
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  distribution of prescription drugs, in violation of
  Title 21, United States Code, Sections 331(t),
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  333(b)(1)(D), also a Class C felony, punishable up to
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10 years, a \$250,000 fine, 3 years of supervised release; and conspiracy to commit money laundering, in violation of Title 18, United States Code, Section 1956(h), a Class C felony, punishable up to 20 years in prison, a \$500,000 fine, a special assessment of \$100, and 3 years of supervised release.

This 34-year-old defendant was involved in the illegal importation and distribution of misbranded drugs for distribution and sale to doctors, medical practices, and hospitals in the United States. December 3, 2014, a 25-count indictment was issued 12 dagainst him and others charging him in 17 counts pertaining to the illegal importation and unlicensed sale of misbranded drugs together with a notice of forfeiture of over \$18 million. He was arrested in Florida on December 24, 2014, and released on February 18, 2015, in this district on personal recognizance and conditions, which he has fully complied with. On March 9, 2015, he pled guilty to 5 of the 17 counts against him which the Court has just identified.

The Court has reviewed and independently determined the quideline sentence applicable to the defendant and his offenses. The defendant has filed a number of objections to the guideline sentence as

calculated by Pretrial Services, and the Court will consider those at this time.

First, the defendant objects to the reference in paragraph 41 of the presentence report to a March 20, 2013, e-mail from another coconspirator, Tzvi Lexier, regarding a doctor complaining that five out of ten patients went to the emergency room after suffering side effects from Botox injections. The objection is on the grounds that the e-mail is not supported by any evidence or corroboration.

The government has not provided in the face of this objection any additional information in support of the claims made in the e-mail, and there's no other evidence in the presentence report that the defendant at the time had received a copy of the e-mail or otherwise knew the substance of the e-mail. For that reason, the Court will strike the reference in the e-mail to paragraph 41 in the presentence report, and the presentence report will be amended accordingly.

Second, with respect to a second objection, the defendant objects to the assessment of a 4-level enhancement pursuant to Section 3B1.1 for leaders and organizers. The Court has considered the arguments of the defendant and the government, statement of facts, and all other information available to the Court, as

well as the substance and commentary of that section and concludes that while the defendant was not an organizer of the conspiracy, owner of the corporate defendants, or an ultimate decision maker, he was, in fact, a commissioned salesperson.

He, nevertheless, engaged in activities beyond that of a mere salesman. Those activities included activities of a managerial or supervisory nature, including the training of various members of the sales team, including training how to mislead clients, instructing drop-shippers on when and how to ship packages, including advising them to use false names and addresses and to ship cold chain products at room temperature.

For these reasons, the Court concludes that an enhancement is appropriate but that the enhancement should be 3 levels rather than 4 levels.

Third, the defendant objects to using the total profits gained during the conspiracy for the purposes of calculating the guidelines. In that regard, the defendant claims that the appropriate amount to be used is the amount of his profits obtained during his participation, which is approximately \$1.3 million, principally on the grounds that Lexier did not inform him of the profitability of the business

overall and Burke had no independent ability to determine that profitability.

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Here the loss amount to be used under the quidelines is that amount paid for the misbranded drugs with no credit for the value of those items or services. Second, the loss amount attributable to any particular defendant is that amount reasonably foreseeable, that is that pecuniary harm that the defendant knew under the circumstances, reasonably should have known was a potential result of the offense.

In this case, given the defendant's position and the overall involvement with the sales activities of the corporate defendants, the Court concludes that under the structure of the sentencing guidelines and the principles applicable to calculating the guidelines, there is sufficient evidence that the defendant was on notice of the overall business of the corporate defendants.

For that reason, it is appropriate that the loverall gain that resulted from the offense be used to calculate the guideline sentence even though he may not have known or had access to the specific overall 24 profitability figures. Nevertheless, as the Court will discuss in a moment, the Court has considered and will

consider the amount of the actual gain that this particular defendant obtained in assessing an overall sentence.

calculates the guideline sentence as follows: The base level is 6 increased by 20 levels to reflect the total gain as defined under the guidelines, an additional 2 levels because a significant part of the offense was committed outside of the United States, an additional 2 levels for his conviction under Section 1956 of Title 18, an addition 3 levels for his role resulting in an overall offense level of 33. The defendant has accepted responsibility and, therefore, is entitled to a 2-level reduction. The government has moved for an additional 1-level reduction based on his acceptance of responsibility, which the Court grants, resulting in an overall offense level of 30.

This is the defendant's first criminal conviction and, therefore, he's in Category I. The guideline sentence for an offense level 30 and criminal history I is 97 to 121 months. The defendant is eligible for probation under the statutory provision but not under the guidelines. Supervised release is recommended of 1 to 3 years with a fine of \$15,000 to \$150,000 with a \$100 special assessment as to each of

the five counts.

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The Court has also considered the sentencing objectives under Section 3553 in light of all of the information available to the Court in the presentence report and the statement of facts. In that regard, the Court has considered the nature and seriousness of the offense which involved a conspiracy that began in approximately April 2011 and continued through the defendant's arrest in December 2014 all for the purposes of smuggling into the United States and distributing within the United States misbranded 12 prescription drugs and devices.

The members of the conspiracy were located both in Canada and the United States and purchased from coconspiring foreign suppliers prescription drugs and devices manufactured and labeled for use in foreign countries, including Turkey, Canada, France, Italy, the United Kingdom, and other countries. They then caused these drugs to be shipped into the United States, often through circuitous routes to conceal the identity of these drugs and their sources of supply.

These illegally imported drugs included orthopedic injections, rheumatological infusions, cosmetic devices, optomology products, and oncology drugs, including numerous drugs that required

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temperature controls during shipment and storage, including such drugs as Botox and Lucentis, which is an injectable prescription drug to treat macular degeneration, as well as other drugs not approved for use in the United States. In order to avoid the regulatory functions of the FDA, Customs and Border Protection, and Immigration and Customs Enforcement-Homeland Security Investigations, members of the conspiracy engaged in a wide variety of actions to accomplish their illegal purposes, including breaking up large shipments of 12 prescription drugs and devices into smaller packages to be sent to the United States to multiple locations under multiple names over multiple days to be consolidated upon arrival after evading border detection, shipping packages through the United Kingdom-based services that allowed packages to be delivered through the United States Postal Service with less scrutiny, placing on Customs forms misleading statements about the packages' contents and value, and addressing packages to members of the conspiracy under false names and titles. There was frequent mishandling of prescription drugs subject to strict temperature requirements, such as cold chain products required to

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be kept at a constantly low temperature for safe use and failure to keep and provide appropriate records to track the proper shipping and storage and transaction history of drugs.

There also was the misbranding of these smuggled and distributed prescription drugs, to include inadequate directions for their use, the so-called FDA black-box warnings, which are the strongest FDA warnings required, as well as the required FDA approval labels. In some instances, the labels failed to bear the required information in the English language.

Once in the United States, the drugs were forwarded to doctors and medical practices or alternative locations, including the personal residences and mailboxes of conspiring individuals known as drop-shippers in the United States. These drop-shippers regularly received packages of prescription drugs and devices from abroad, removed labels and other *indicia* showing that they had been imported from abroad. They repacked the orders and reshipped them to doctors and medical practices throughout the United States in order to give the false impression that the drugs were being distributed domestically and legally.

The drugs used for the storage and handling

of prescription drugs consisted of such things as unregistered commercial mailboxes, as well as the backyards of personal residences, porches, basement rooms, garages, kitchens, and other areas of storage, none of which had the required lighting, ventilation, temperature, humidity, or security required for the safe handling and storage of prescription drugs.

Neither the defendant nor any of his codefendants were licensed to sell or distribute prescription drugs within the United States.

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Once funds were obtained from the illegal distribution of drugs, they were deposited into bank accounts of the corporate defendant. Those funds were then used to pay foreign suppliers of prescription drugs, as well as commissions to the salespersons who sold the drugs, as well as drop-shippers, and to the owners of the corporate defendants.

As stated in the statement of facts, overall, the conspiracy caused to be illegally imported and distributed misbranded prescription drugs and devices in the United States amounting to over \$18 million; although, the amount of \$33 million has been cited in related cases with this particular defendant receiving personally approximately \$1.3 million.

As stated in the statement of facts admitted

under oath by Mr. Burke, his role was to participate in the day-to-day operations of the corporate defendants. In that role in working with the owner of the corporate defendants and others, he communicated with 5 coconspirators or sales representatives and drop-shippers in the United States. He tracked and 7 coordinated shipments from overseas into the United States. He called the United States-based customers to sell prescription drugs and devices from abroad and 10 engaged in the illegal importation and sales of misbranded drugs using false names in connection with 12 his activities.

There's no doubt that the defendant was centrally involved in the overall operations of a substantial and extensive illegal importation and distribution scheme. Whatever may have been the defendant's initial assumptions about the legality of what he was doing, there's no doubt that he quickly understood what he was doing was improper and illegal and continued and expanded his activities nonetheless over time with what would appear to be rather comprehensive knowledge concerning the overall scope and operation of the scheme.

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The Court also has no doubt that the defendant's activities substantially contributed to the

ability of these corporate defendants and others to successfully import and distribute these misbranded and improperly transported and stored drugs, that he did so knowing that what he was doing was illegal, and that as a result, he knowingly and substantially contributed to the distribution of drugs and devices that threatened the public safety.

As to the defendant's personal history and characteristics, this is the defendant's first involvement in the criminal justice system, and the Court has considered the extensive information and material that has been provided to it concerning his mental health issues, his educational, vocational, and employment histories and capabilities, including the many letters it has received from family and friends that have spoken to his many good aspects.

It's against this information the Court has considered the guideline sentence and the extent to which it would appropriately reflect the level of culpability of this particular defendant. In that regard, the Court has considered the guideline sentence was substantially driven by the \$18 million figure used to calculate the loss amount even though the loss amount does not reflect any particular loss. The Court has also considered that in other contexts, the

defendant's gain of approximately \$1.3 million would be used to calculate the guideline sentence. The Court has considered that guideline sentence were it calculated on that basis.

The Court has also considered the public interest in this case, which includes both the need for general and specific deterrence. With respect to specific deterrence, the Court has considered the defendant's background and prospects for recidivist behavior, which the Court considers very low.

With respect to general deterrence, the Court has considered, as I indicated, the public interest and the role the defendant played within that scheme, the dangers presented to the public by the distribution of these drugs in the fashion that they were, and the defendant's substantial role in the sales and distribution of those drugs, including the volume of drugs, the length of time he performed those activities, his continued involvement in those activities after clear and unmistakable warnings that his activities were illegal, as well as the extent to which others had assisted in his efforts.

The Court has also considered that while there were occasional counterfeit drugs, these drugs were for the most part drugs that had been manufactured

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by the respective pharmaceutical companies and were not counterfeit drugs. But having said that, the Court has also considered that the manner in which these drugs were shipped and treated gives little comfort to the Court that the activities were any less dangerous than they were.

The Court has also considered the public interest in terms of alternative sentences that can satisfy the sentencing objectives and also the public interest in fashioning a sentence that allows this first-time offender to rejoin the community and his family within a reasonable period of time and resume what the Court has every confidence can be a productive and law-abiding life.

The Court has considered in that regard the defendant's age, as well as the need to avoid unwarranted sentencing disparities. In that regard, the Court has considered the defendant's level of culpability relative to others in the conspiracy, the sentences already imposed on coconspirators, and the sentences imposed in other cases of this type within this court and elsewhere. The Court has also considered the defendant's acceptance of responsibility, as well as his immediate cooperation.

At the end of the analysis, the Court is

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faced with a defendant who has obtained substantial
  benefit through a fraudulent scheme that itself had
  posed substantial damages or substantial risks and
   threats to the safety of the public, and the Court has
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  considered sentences in other cases that have similar
  characteristics.
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             The Court is in a position to impose sentence
  at this time.
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             Mr. Burke, would you come to the podium,
  please.
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             Mr. Burke, it will be the sentence of this
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  Court you be committed to the Bureau of Prisons for a
  period of 26 months following which you'll be placed on
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  1 year of supervised release. The Court will not
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  limpose a fine at this time in light of your forfeiture
  obligation. The Court will impose a $500 special
  assessment for each of the counts. The sentence and
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  the supervised release of 1 year applies to each of the
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  5 counts and will be served concurrently. That will be
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   the sentence of the Court.
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             Is there anything further?
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             MR. AGNIFILO: Thank you.
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             THE DEFENDANT:
                             Thank you.
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             MR. DWYER: Your Honor, the government has a
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   joint order of forfeiture which has been signed by the
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defendant, as well as defense counsel.
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        (Documents are handed up to the Court.)
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             MR. AGNIFILO: Your Honor, the only issue is
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  II believe we're trying to effect a change in the bond.
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  Mr. Burke's sister -- and she wrote a letter to this.
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             THE COURT: I've seen it. The third-party
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  custodian needs to be changed?
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             MR. AGNIFILO:
                            Yes.
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             THE COURT: All right. Any objection by the
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  government on that?
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             MR. DWYER: No, Your Honor.
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             THE COURT: Mr. Burke, come to the podium.
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             I'm going to allow you to voluntarily
  surrender at a time and place to be designated to you
  by the Bureau of Prisons through the Pretrial Services
  and Probation office under whose supervision you'll
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  continue.
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             I'm also going to modify the conditions of
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  your bond to change the third-party custodian from your
  sister to I believe --
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             What's the name of the individual?
             THE DEFENDANT: Aaron and Daniella Schwartz.
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             THE COURT: -- Ms. Schwartz, who has been
  reviewed and approved by Pretrial Services. You'll
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  remain under her custody until reporting to the Bureau
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of Prisons.
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             THE DEFENDANT: Yes. Thank you.
             MR. AGNIFILO: Would Your Honor consider
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 4 recommending Otisville?
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             THE COURT: In New York?
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             MR. AGNIFILO: Yes, Judge.
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             THE COURT: Yes. The Court will make that
 8 | recommendation to the Bureau of Prisons if it's
  available and appropriate.
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             MR. AGNIFILO: Thank you, Judge. I
11 appreciate it.
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             THE COURT: All right. Anything else?
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             MR. DWYER: Nothing from the government, Your
14 Honor.
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             THE COURT: All right. Counsel and the
16 defendant are excused.
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             The Court will stand in recess.
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                       Time: 9:50 a.m.
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        I certify that the foregoing is a true and
22
    accurate transcription of my stenographic notes.
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                            Rhonda F. Montgomery, CCR, RPR
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